ADDITIONAL FEE

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

REMARKS

Applicants respectfully request reconsideration and allowance of this application in view of the following comments.

The sole issue for consideration is the rejection of claims 1-4 under 35 USC § 102(e) as being anticipated by Bourke et al. ("Bourke"), U.S. Patent No. 5,637,320. The Examiner finds that Bourke teaches a formulation for oral administration in a multiparticle form, wherein a first portion is designed as a sustained release medicament, and a second portion is designed as a rapid release medicament, and, further, that Bourke's teaching anticipates the present claims. In response, Applicants would remind the Examiner that anticipation requires that each and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference, and, further, if the Examiner relies on a theory of inherency as to any particularly element, then the extrinsic evidence must make clear that such element is *necessarily* present in the thing described in the reference, and the presence of such element therein would be so recognized by persons skilled in the art. *In re Robertson*, 49 USPQ2d 1949, 1950-51 (Fed.

Cir. 1999). Further, inherency is not established by probabilities or possibilities, and the mere fact that a property *may* result from a given circumstances is not sufficient; instead it must be shown that such property *necessarily* inheres in the thing described in the reference. *Id.* The Examiner has not explained how Bourke's single active ingredient naproxen satisfies both of elements A and B according to the instant claims, nor has the Examiner meaningfully dealt with any of the specific limitations of dependent claims 2-4. In short, Applicants believe that this rejection is improper, and, further, that the Examiner would be fully justified to reconsider and withdraw this rejection.

Further on this point, it is Applicants' opinion that Bourke does neither anticipate nor render obvious the subject-matter of the present invention. As can be gathered from this prior art document, column 1, line 60, to column 2, line 2, Bourke describes a naproxen formulation wherein the drug is formulated in two different manners. In a first portion, the drug is formulated such that a controlled release of naproxen is obtained leading to a maintenance of therapeutically effective blood levels over 24 hours. In a second portion, the naproxen is formulated such that it is immediately released. However, this does not mean that an immediate onset of action caused by naproxen can be observed. Namely, as already described in the present application, page 2, line 25, naproxen belongs to the group of systemically acting analgesics. As also described in the present application, page 1, line 21 to 23, such systemically acting analgesics reach their maximum activity not until after about 1 to 2 hours. Moreover, as described in the original

description, page 3, line 7 to 10 such systemic analgesics show a significant onset of action only after 15 min. lasting for up to 24 hours. Therefore, regardless in which way naproxen is formulated, it does not show rapid onset of action. This, however, is required according to the present invention for the combination element A, i.e. the locally acting analgesic. As explained in the original description page 1, lines 30 to 32, the element A has to show a significant onset of action, for example, within a period of at most 10 min., preferably within a much shorter period of time. This cannot be realized by the use of naproxen as element A since as explained above naproxen by its nature is not able to cause such a rapid onset of action.

Moreover, claims 2 and 3 require particular time durations, and the naproxen formulations of Bourke have not been shown to satisfy these limitations.

In view of the forgoing, Applicants submit that the prior art cited by the Examiner does not anticipate the subject-matter of the present invention. Moreover, since this prior art only mentions naproxen formulations, there is also no hint therein to use beside naproxen a second active substance which shows immediate significant onset of action, i.e. an element A according to the present invention. Therefore, the prior art cited by the examiner does also not render obvious the subject-matter of the present invention.

Applicants believe that the foregoing constitutes a bona fide response to all outstanding

objections and rejections.

Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (914) 332-1700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

Respectfully submitted,

NORRIS McLAUGHLIN & MARCUS, P.A.

By _____
Kurt G. Briscoe
Reg. No. 33,141

KGB:ja
660 White Plains Road
Tarrytown, New York 10591-5144
(914) 332-1700

CERTIFICATE OF MAILING

I hereby certify that the foregoing Request for Reconsideration under 37 CFR § 1.111 is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date indicated below:

Date: 8-8-00

By _____
Kurt G. Briscoe